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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,372	02/26/2004	Gottfried Mueller	HOE-803	5135

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EXAMINER

DOWE, KATHERINE MARIE

ART UNIT	PAPER NUMBER
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3734

DATE MAILED: 09/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/789,372	Applicant(s) MUELLER ET AL.	
	Examiner Katherine M. Dowe	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. DE 103 10 995.1 filed on March 6, 2003.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 4, 5, 7-20, 23-26, and 28-36 are rejected under 35 U.S.C. 102(b) as being anticipated by King et al. (US 3,874,388). Regarding claims 1 and 2, King et al. disclose a closure device (see Fig 1C) comprising a plurality of wings (81) with bearing areas (82) and a base part (84). Furthermore, the wings are held by hinge joints (Fig 4, element 86') that allow the wings to be movably attached to the base part (col 6, lines 39-41).

Regarding claims 4 and 14, King et al. disclose the wing joints (see Fig 2B, element 86) are oriented at a right angle to the base part (84a). Thus, the wings are oriented at a right angle to the central axis of the base part when the device is in the flapped-out position (See Fig 9E, where element 3 is along the central axis of the base

part and elements 83 form a perpendicular axis). Furthermore, King et al. disclose a ring element (Fig 2B, element 87) to prevent the wings from opening past 90 degrees (col 6, lines 42-44).

Regarding claim 5, King et al. disclose the wing joints lie parallel to tangents to an outer circumference of the base part (see Fig 9B – 9D). Thus, the wings emanate out from the central axis of the base part in at least a generally perpendicular, radial direction when in the flapped-out position and in at least a generally parallel, axial direction when in the flapped-in position (col 12, lines 28-33).

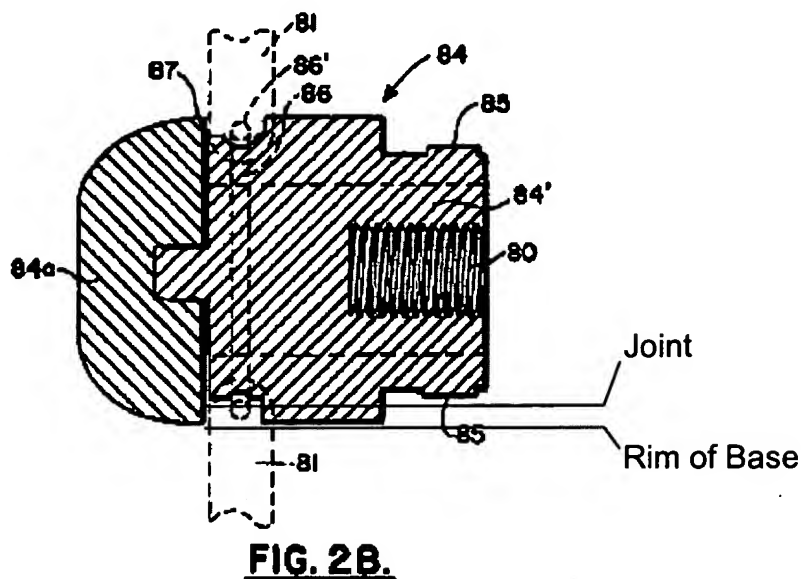
Regarding claims 7 and 11, King et al. disclose the wings (col 6, line 21) and the base part (col 6, line 34-35) are made of stainless steel and are, therefore, of substantially rigid design.

Regarding claims 8 - 10, King et al. disclose the wings hold bearing elements spanned between adjacent wings (Fig 10B, element 82; col 12, line 41). The bearing elements are made of bendable material (col 6, lines 49-55) and are folded when the closure device is in the flapped in position (Fig 2A, element 82).

Regarding claim 12, King et al. disclose the wings are hinged to the base part such that in the flapped-in position, the wings do not protrude laterally over base part (Fig 2A and Fig 2B) to ensure the wings do not occupy any additional space within the trocar sheath, or catheter (col 7, lines 18-20).

Regarding claim 13, King et al. disclose the wings form and/or hold bearing areas on the tissue when the device is flapped out (Fig 10B, elements 81 and 82).

Regarding claim 15, King et al. disclose the joints are set back from a circumferential rim of the base part (see Fig 2B below).



Regarding claim 16, King et al. disclose the joints (Fig 2B, element 86) are seated on the upper side of the base part facing the tissue (right end of element 84a).

Regarding claims 17-19, King et al. disclose at least two wings (Fig 2A, element 81), wherein the wings are diametrically disposed and arranged around the circumference of the base part (see arrangement of grooves in the base part adapted to fit the wings - Fig 2C, element 89).

Regarding claim 20, King et al. disclose the base part has a round outer cross section (see Fig 2C).

Regarding claim 23, King et al. disclose the wings may extend at an incline to the base part when in the flapped-in position (Fig 2A, element 82). King et al. disclose the

wings should be at least generally parallel to the central axis of the base part, not completely straight (col 12, lines 28-33).

Regarding claims 24-26, King et al. disclose a ring-shaped element (Fig 2B, element 87) on the base part (84) that provides a bearing surface to prevent the wings from opening past 90 degrees (col 6, lines 42-44). Thus, the base provides a bearing area to inhibit swiveling of the wings beyond a bearing position. The wings comprise a support for placement against the associated bearing areas (Fig 2B, distal end of wing 81).

Regarding claims 28-30, King et al. disclose a coupling on the base part for a holding mandrel (Fig 2A, element 3). The coupling includes a central threaded orifice on the proximal end of the base part (Fig 2B, element 80) that mates with the threaded end of the holding mandrel, or guide wire (Fig 5, element 31). King et al. disclose the base part (Fig 2B, element 84) has a holding element (84') and a ring element (87), wherein the ring element prevents the wings from opening beyond 90 degrees (col 6, lines 41-42). Furthermore, the ring element is held in the fashion of a snap closure on the holding element, wherein the proximal end of the base (84a) fits over the protrusion of the distal end of the holding element (84') with a close tolerance thereby sandwiching the ring element (87).

Regarding claims 31 and 32, King et al. disclose a closure device (see Fig 1C) comprising a plurality of wings (81) with bearing areas (82) and a base part (84). Furthermore, the wings are held by hinge joints (Fig 4, element 86') that allow the wings to be movably attached to the base part (col 6, lines 39-41). King et al. disclose an

applicator device for the said closure device comprising a longitudinally displaceable positioning element (Figs 9C-9D, element 2) that transfers the closure device from the flapped-in position to the flapped-out position. The positioning element comprises bearing areas for the wings for swiveling the wings out (col 9, lines 35-37).

Regarding claims 33-36, King et al. disclose a holding mandrel to hold and position the closure device (Figs 9B-9E, element 3). Furthermore, King et al. disclose the positioning element (2) surrounds the holding mandrel (3) at least partially (col 7, lines 59-60). The holding mandrel can be displaced longitudinally within the positioning element to guide the closure device (Figs 9B-9E; col 9, lines 30-32). Finally, King et al. disclose the positioning element (Fig 9c, element 2) provides a centering means for the holding mandrel (3) by acting as a guide through the outer trocar sheath, or catheter (1).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. (US 3,874,388) in view of Redmond et al. (US 6,613,070). King et al. disclose a closure device in which a plurality of wings are attached to a base part by means of hinge joints. However, King et al. does not disclose the joints are film hinges or that the wings are integrally held on the base part. Redmond discloses a vascular sealant delivery device incorporating an articulating foot (Figs 18A and 18B, element 208) that must be sufficiently flexible to shift between its non-deployed, or flapped-in, position (Fig 18B) to its deployed, or flapped-out, position (Fig 18A). Redmond teaches a variety of mechanisms for an articulated, or pivotable, attachment of the foot to the shaft (206) that may be utilized, including a living, or film, hinge (col 11, lines 25-32). Furthermore, by definition a living hinge works by weakening a region in the material

where pivotable movement is desired (col 11, line 30) and thus the two hinged segments must be integrally formed. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the surgical closure device of King et al. to form the wings integrally on the base part and incorporate film hinges.

7. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. (US 3,874,388) in view of Rousseau (US 6,616,685). King et al. disclose a closure device comprising a plurality of wings. However, King et al. do not disclose the wings increase in width away from the base part. Rousseau discloses a similar closure device comprising a plurality of petal shaped wings, which increase in width away from the center base part (Fig 2, element 12; col 2, lines 17-18). Rousseau teaches the wing design allows for spiral overlapping of the wings and thus the closure device is able to form a flat disc and come in direct contact with the tissue defect (col 1, lines 46-48). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the wings of the surgical closure device of King et al. such that the width of the wings increased away from the base part.

8. Claims 21, 22, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. (US 3,874,388) in view of Himpens et al. (US 5,397,331). King et al. disclose a closure device and applicator device substantially as claimed; however they disclose the closure device is secured to the tissue by anchoring methods

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utilizing small projections or barbs (col 6, lines 21-24) and do not disclose securing the closure device to the tissue with suturing methods. Himpens et al. disclose a similar closure device that is secured to the surrounding tissue by suturing means. The base part (Fig 4, element 16) has a pin (18) through which the suture (19) passes and by means of which the suture is held. Himpens et al. teaches the suture is used to secure the closure device in its proper position and is threaded through the holding mandrel to enable simple and quick handling of the device (col 2, lines 56-60). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the securing mechanism of the surgical closure device of King et al. to incorporate sutures and thread the suture through the holding mandrel for easy insertion.

9. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over King et al. (US 3,874,388) in view of Shichman et al. (US 6,197,041). King et al. disclose a closure device and applicator device substantially as claimed. However, they do not disclose a reducing sleeve is provided to position the positioning element. Shichman discloses a similar trocar assembly that includes a reducing sleeve that surrounds the insertable device (Fig 2B, element 130). Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the applicator device of the surgical closure device of King et al. to incorporate a reducing sleeve to create a tight fit for the insertable device and prevent unwanted swiveling.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine M. Dowe whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Hayes can be reached on (571)272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

kmd



MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER